



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2011-0689; FRL-9332-6]

Pesticide Experimental Use Permit; Receipt of Application; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's receipt of an EUP for the Plant-Incorporated Protectants (PIPs) *Bacillus thuringiensis* Cry proteins Cry1Ab, Cry2Ae, Vip3Aa19, and full-length Cry1Ab in event T304-40, GHB119, COT102, and COT67B cotton plants, respectively; and the PIP *Bacillus thuringiensis* combined trait cotton, T304-40 X GHB119 X COT102 X COT67B; and the combined trait cotton necessary for their production. The Agency has determined that the permit may be of regional and national significance. Therefore, in accordance with 40 CFR 172.11(a), the Agency is soliciting comments on this application.

DATES: Comments must be received on or before *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2011-0689, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2011-0689. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8263; e-mail address: greenway.denise@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons who are interested in agricultural biotechnology or may be required to conduct testing of pesticidal substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any

questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.

- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What Action is the Agency Taking?

Under Section 5 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136c, EPA can allow manufacturers to field test pesticides under development. Manufacturers are required to obtain an EUP before testing new pesticides or new uses of pesticides if they conduct experimental field tests on 10 acres or more of land or one acre or more of water.

Pursuant to 40 CFR 172.11(a), the Agency has determined that the following EUP application may be of regional and national significance, and therefore is seeking public comment on the EUP application:

Submitter: Bayer CropScience, (264-EUP-RUT).

Pesticide Chemical: Plant-Incorporated Protectant Combined Trait *Bacillus thuringiensis* Cotton T304-40 (Produces Cry1Ab Protein) X GHB119 (Produces Cry2Ae Protein) X COT102 (Produces Vip3Aa19 Protein) X COT67B (Produces Full-length Cry1Ab Protein), and the Combined Trait Cotton necessary for their production, along with the individual events T304-40, GHB119, COT102, and COT67B.

Summary of Request: Bayer CropScience is proposing an experimental program to allow plantings for the evaluation of these cotton plant lines between October 1, 2011 and June 1, 2013. Testing the efficacy of insect resistance transgenes and agronomic performance, as well as the production of sample material for regulatory studies, is intended. The applicant requests to conduct testing in the U.S. territory of Puerto Rico and in 12 states: Alabama, Arkansas, Arizona, California, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee and Texas. Testing is proposed to be conducted on a total of 12,210 acres, of which 2,035 acres will be planted to test PIP materials and 10,175 acres to test non-PIP materials. The proposed experimental program requires up to 0.04 pound of Cry1Ab protein, up to 0.17 pound of Cry2Ae protein, up to 0.08 pound of Vip3Aa19 protein, and up to 0.26 pound of full-length Cry1Ab protein. The company is researching the potential for *Bacillus thuringiensis* proteins produced by the inserted genetic material in these cotton PIPs for control of the lepidopteran larvae cotton pests cotton bollworm (*Helicoverpa zea*), tobacco budworm

(*Heliothis virescens*), pink bollworm (*Pectinophora gossypiella*), fall armyworm (*Spodoptera frugiperda*), and beet armyworm (*Spodoptera exigua*).

A copy of the application and any information submitted is available for public review in the docket established for this EUP application as described under

ADDRESSES.

Following the review of the application and any comments and data received in response to this solicitation, EPA will decide whether to issue or deny the EUP request, and if issued, the conditions under which it is to be conducted. Any issuance of an EUP will be announced in the **Federal Register**.

List of Subjects

Environmental protection, Experimental use permits.

Dated: January 9, 2012.

W. Michael McDavit,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

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